

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

TRANSLATION
PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing (day/month/year) **See form PCT/ISA/210**

Applicant's or agent's file reference

03706pct

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/EP2005/001691

International filing date (day/month/year)

18.02.2005

Priority date (day/month/year)

19.02.2004

International Patent Classification (IPC) or both national classification and IPC

G01N33/543, G01N33/52, G01N21/76, G01N21/01, B01L9/00, B26F1/38

Applicant

PRIONICS AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/IEP

Authorized officer

Facsimile No.

Telephone No.

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Box No. I

Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 33-40

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 33-40

On account of an objection raised by the ISA in respect of lack of unity of invention, no international search report has been prepared for claims 33-40. Therefore, for the said claims, no expert opinion can be given on novelty, inventive step and industrial applicability either.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
- ☐ paid additional fees under protest
- ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
- ☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☐ all parts

☒ the parts relating to claims Nos. 1-32, 41

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement			
Novelty (N)	Claims	<u>3, 8-23, 27, 28, 30-32, 41</u>	YES
	Claims	<u>1, 2, 4-7, 24-26, 29</u>	NO
Inventive step (IS)	Claims	<u>27, 28, 41</u>	YES
	Claims	<u>1-26, 29-32</u>	NO
Industrial applicability (IA)	Claims	<u>1-32, 41</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations:

1. Reference is made to the following documents:

D1: EP 0840123, 6 May 1998
D2: WO 03/029813, 10 April 2003
D3: WO 99/41596, 19 August 1999
D4: EP 0618443, 5 October 1994
D5: US 2004/162690, 19 August 2004

2. Document **D1** (see the passages cited in the international search report) discloses a device for determining analytes by means of test strips consisting of a first, block-shaped support element having a recess for accommodating the test strip, and also a second, frame-shaped fixing element which serves for fixing (= positioning) the test strip in the support element. This device is therefore to be considered a positioning device within the meaning of the present application.

The test strip used has (preferably linear) isolated regions having analyte-binding biomolecules. After sample administration has proceeded and formation of colored detection regions on the test strip, quantitative evaluation proceeds using a scanner which transmits the detected image data to computer-based image processing software.

D1 discloses the subject matter of the present claims 1, 2, 4-7 and 29, which are therefore not novel (PCT Article 33(2)).

In addition, **D1** also discloses the subject matter of the present

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability:
citations and explanations supporting such statement

claims 24-26, for example such as can be seen from the drawings and column 9/lines 4-42. These claims are also therefore not novel (PCT Article 33(2)).

3. **D2** (see the passages cited in the international search report) describes a frame-shaped test strip holder for one or more test strips for mounting onto a microtiter plate. The test strip holder is suitable for image detection via an image producing device, since in the case of such an evaluation method, only the relative positioning of the CCD or the like of the image producing device and of the test strip holder is of importance.

D2 discloses the subject matter of the present claims 24 and 25, which are therefore not novel (PCT Article 33(2)).

4. Document **D3** (see the passages cited in the international search report) discloses a device for analyzing urine samples by means of test strips which are moved past a light source and a light intensity detector on a holding or transport unit, which light intensity detector is coupled to an image evaluation unit for color intensity and pattern recognition.

The device of claim 1 differs from that disclosed by **D3** in that the latter does not have a positioning device for the test strips.

The use of such a positioning device in evaluation devices and methods for test strips, however, is generally known, cf., e.g., **D1** or else **D4** (paragraph 5, bottom); the solution proposed in independent claim 1 therefore cannot be considered inventive (PCT Article 33(3)).

5. Document **D4** (see the passages cited in the international search report) discloses an analytical system for test strips which has a holding and positioning device for the test strips in order to place it in a reproducible definite position relative to the measuring unit.

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

The device of claims 1, 2 and 7 differs from that disclosed by **D4** in that the latter, instead of an image-forming method, uses a conventional photometric detection system for detecting the analyte bound to the test strips.

Image-forming methods (for example consisting of a scanner coupled to a computer) for the evaluation of test strips, however, are generally known, see, e.g., **D1** or **D3**; the solution proposed in claims 1, 2 and 7 cannot therefore be considered inventive (PCT Article 33(3)).

5. The objections raised under PCT Article 33(3) to the device according to claim 1 also apply, *mutatis mutandis*, to claim 29.
6. Claims 3-6, 8-23 and 30-32 do not contain any features which, in combination with the features of any claim to which they refer back, meet the PCT requirements for novelty and inventive step, since these are either disclosed by documents **D1-D4** or are technical alternatives familiar to any person skilled in the art (PCT Article 33(3)).
7. **D5** (see the passages cited in the international search report) describes a method and a device for optical analysis of one or more test strips, using a computer-coupled scanner. The method uses a template in which one or more test strips are brought to and held in a defined position relative to the scanner. The test strips can be furnished with identifying features such as, for example, a barcode.

If the priority of the present application should be invalid, **D5** is considered prejudicial to novelty for claims 1-7, 10-12, 22, 29 and 31.
8. The subject matter of claims 27, 28 and 41 is not disclosed or rendered obvious by any of the documents mentioned in this opinion; these claims therefore meet the preconditions of PCT Article 33(2) and (3).

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Contrary to PCT Rule 5.1(a)(ii), the description does not indicate the relevant prior art disclosed in documents **D1-D3**.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The application does not meet the requirements of PCT Article 6, because claims 9, 12, 14, 16 and 19-23 lack clarity.

The said technical features in the device claims mentioned do not relate to the structural definition of the device or its parts, but relate only to the later analytical method using the device. The intended restrictions, therefore, contrary to the requirements of PCT Article 6, are not clearly derived from the claim.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box IV

The various inventions are:

- Claims 1-23, 29-32: Device and method for the optical evaluation of test strips.
- Claims 24-28: Positioning device for test strips.
- Claims 33-40: Test strip unit having a plurality of linked test strips.
- Claim 41: Punch method for producing a test strip unit.

For the following reasons, these inventions are not so linked as to form a single general inventive concept (PCT Rule 13.1):

Invention 1 relates to a device and a method for the optical evaluation of test strips, their technical features, the combined use of a test strip or a test strip unit, a positioning device and an image producing device.

The technical features mentioned in invention 2 are in no way a restriction to the sole use of the claimed positioning device within invention 1; although a formal back reference to the claims of invention 1 is present, the claimed positioning device, however, is only to be considered suitable for use in the context of invention 1 (however it could also be used in a completely different method or in a completely different device).

The technical features mentioned in invention 3 are in no way a restriction to the sole use of the claimed test strip unit within invention 1 or 2; although a formal back reference to the claims of inventions 1 or 2 is present, the claimed test strip unit, however, is only to be considered suitable for the use in the context of invention 1 or 2 (but it could also be used in a completely different method, a completely different device or a completely different positioning device).

The punch method mentioned in invention 4 relates to a completely different technical field; said technical features are in no way a

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Supplemental Box

restriction to the sole use of the claimed punch method for producing a test strip unit according to invention 3; the claimed punch method may well be suitable for its production, but it can also be used for producing completely different things (not only test strips!).